AUG 2 8 2008

K080405

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

PROPRIETARY NAME:	Sygnal™ DBM
COMMON NAME:	Bone Void Filler Containing Human Demineralized Bone Matrix (DBM)
REGULATORY CLASS:	Class II
CLASSIFICATION IDENTIFICATION:	21 C.F.R. §888.3045 Resorbable calcium salt bone void filler device
PRODUCT CODE:	MBP, MQV
PANEL CODE:	87—Orthopedic Devices
SPONSOR:	Musculoskeletal Transplant Foundation 125 May Street Edison, NJ 08837 732-661-0202 723-661-2189 fax

INDICATIONS FOR USE:

Sygnal DBM is a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Sygnal DBM can be used alone or as an extender in the posterolateral spine with bone marrow. It is indicated for use in the treatment of surgically-created osseous defects or osseous defects created from traumatic injury.

Sygnal DBM is for single patient use only.

DEVICE DESCRIPTION:

Sygnal DBM is completely resorbable and is composed of donated cortical bone. The bone granules are mixed with sodium hyaluronate (Hy) and carboxymethylcellulose (CMC). Sygnal DBM is available in sizes of 0.5 cc, 1.0 cc, 2.5 cc, 5.0 cc, and 10.0 cc.

SAFETY AND EFFECTIVENESS INFORMATION:

Biocompatibility of Sygnal DBM components has been established through their long history of safe and effective clinical use, further supported by laboratory testing conducted per ISO 10993. Sygnal DBM is single-donor processed using aseptic techniques and is tested for sterility per current USP <71>.

OSTEOINDUCTIVE POTENTIAL:

Sygnal DBM is osteoconductive, and has been shown to have osteoinductivity potential in an athymic mouse model. Every lot of final product is assayed *in vivo* for its osteoinductive potential. Standard testing performed in an athymic mouse model must prove positive for lot release. Osteoinduction assay results in the athymic mouse model should not be interpreted to predict clinical performance in human subjects.

VIRAL CLEARANCE AND INACTIVATION:

The method for processing the demineralized bone matrix contained in Sygnal DBM was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The DBM processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Musculoskeletal Transplant Foundation
% Ms. Nancy Bennewitz
Regulatory Affairs Submission Specialist
Edison Corporate Center
123 May Street, Suite 300
Edison, New Jersey 08837

AUG 28 2008

Re: K080405
Trade Name: Sygnal DBM
Regulation Number: 21 CFR § 888.3045
Regulation Name: Resorbable Bone Substitute
Regulatory Class: Class II
Product Code: MBP
Dated: August 22, 2008
Received: August 25, 2008

Dear Ms. Bennewitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

INDICATIONS FOR USE

510(k) Number (if known): K080405

Device Name: Sygnal™ DBM

Indications for Use:

Sygnal DBM is a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Sygnal DBM can be used alone or as an extender in the posterolateral spine with bone marrow. It is indicated for use in the treatment of surgically-created osseous defects or osseous defects created from traumatic injury.

Sygnal DBM is for single patient use only.

Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorati
and Neurological Devices

510(k) Number K080405